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DECLARATION OF CONFORMITY (UYGUNLUK BEYANI)

MANUFACTURER: BAYTEKS TEKNİK TEKSTİL SAN. VE TİC. A.Ş

Organize Sanayi Bölgesi 19 Nolu Cad. No:11/2 MERKEZ/KİLİS

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This declaration of conformity has been prepared in MDR 2017/745 Part II, Article 19, Annex IV; The document is arranged in the home page program for all users.

UDI -DI : See the Sterile Products table.
PRODUCT : Sterile Disposable Surgical Gowns, Sterile Disposable Surgical Drapes, Sterile Disposable Surgical Packs.

NOTIFIED BODY : **UDEM Adriatic d.o.o**
R3 Radnička cesta 54/ R3, Green Gold Centar, IV. kat, 10000, Zagreb, Hırvatistan

ID NO : 2696

CND(EMDN) CODE : **See the Sterile Products table.**

SRN NUMBER : TR-MF-000024488

CLASSIFICATION : **Sınıf I Steril-**(MDR 2017/745 - EKVIII/Bölüm III - Madde 4 - Kural 1)

SCOPE : Sterile Disposable Surgical Gowns, Sterile Disposable Surgical Drapes, Sterile Disposable Surgical Packs.

ADDITIONAL : EK XI A

APPLIED STANDARDS : TS EN ISO 13485:2016, ISO 14971:2020, EN ISO 11135:2014, TS EN ISO 15223-1:2021, TS EN ISO 11737-1:2018, EN ISO 11737-2:2020, TS EN ISO 14644-1:2021, TS EN ISO 14644-2:2021, TS EN ISO 10993-1:2021, TS EN ISO 11607-1:2020, TS EN ISO 11607-2:2020, TS EN ISO 11138-1:2017, TS EN ISO 11140-1:2015

The directive for our product is the Council Directive MDR 2017/745 ECC for all versions of medical devices. The Manufacturer of the product, Bayteks Teknik Tekstil San. ve Tic. A.Ş, is responsible for the requirements of this council directive. Our products are not medical devices that contains human blood derivatives, animal products, animal skin, tissues, or blood derivatives or phthalates.

STERILE PRODUCT			
PRODUCT NAME	BASIC UDI	MODEL NO	EMDN
DISPOSABLE FENESTRATED DRAPE 90x75CM	86817441ST30100001331A9	SD-05210-18	T020102
DISPOSABLE FENESTRATED DRAPE 160X200 CM	86817441ST30100003676BU	SD-05210-29	T020102
DISPOSABLE SIDE ADHESIVE DRAPE 140X240 CM	86817441ST301000010139Q	SD-04204-10	T0201
DISPOSABLE SIDE ADHESVIVE DRAPE 75x75 CM	86817441ST301000010139Q	SD-04204-03	T0201
DISPOSABLE SIDE ADHESVIVE DRAPE 75x90 CM	86817441ST301000010149S	SD-04204-20	T0201
DISPOSABLE SIDE ADHESVIVE DRAPE 150x240 CM	86817441ST30100002290AT	SD-04203-04	T0201
DISPOSABLE SIDE ADHESVIVE DRAPE 175x175 CM	86817441ST301000010149S	SD-04202-02	T0201
DISPOSABLE TUR DRAPE 200X250 CM	86817441ST30100002346AV	SD-04803-09	T020102

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DISPOSABLE SURGICAL PACK FOR ANGIOGRAPHY	86817441ST30100001665B9	SP-05004-56	T0202
DISPOSABLE CAMERA COVER 14X250 CM	86817441ST30100002408AS	SU-40011-01	T020102
DISPOSABLE CARDIOVASCULAR BYPASS PACK	86817441ST30100001091AC	SP-05001-32	T0202
DISPOSABLE CARDIOVASCULAR PACK ADULT	86817441ST30100001084AF	SP-05001-18	T0202
DISPOSABLE INSTRUMENT TABLE COVER 160X240 CM	86817441ST301000011239Y	SD-00200-10	T020199
DISPOSABLE INSTRUMENT TABLE COVER 200X240 CM	86817441ST30100000976BN	SD-00200-12	T020199
DISPOSABLE KNEE SURGERY PACK	86817441ST30100001188AU	SP-07002-10	T0202
DISPOSABLE KNEE IMPLANT SURGERY PACK	86817441ST301000010009F	SP-07002-27	T0202
DISPOSABLE PEDIATRIC CARDIOVASCULAR PACK	86817441ST30100004047AW	SP-05001-29	T0202
DISPOSABLE RADIAL ANGIOGRAPHY PACK	86817441ST30100002752BC	SP-05004-56	T0202
DISPOSABLE REINFORCED PLAIN DRAPE 55X70 CM	86817441ST30100004143AT	SD-14209-45	T0201
DISPOSABLE ACUTE THORACIC PACK	86817441ST30100001068AH	SP-09008-35	T0202
DISPOSABLE BRAIN SURGERY PACK	86817441ST30100001801AR	SP-01001-34	T0202
DISPOSABLE CESEREAN PACK	86817441ST30100003947C4	SP-03007-56	T0202
DISPOSABLE CRANIOTOMY PACK	86817441ST30100002329AV	SP-01001-35	T0202
DISPOSABLE CRYOABLATION SURGERY PACK	86817441ST30100002066AL	SP-01001-67	T0202
DISPOSABLE DELIVERY PACK	86817441ST30100002208AG	SP-03001-67	T0202
DISPOSABLE ELECTROPHYSIOLOGY PACK	86817441ST30100002964BV	SP-05004-67	T0202
DISPOSABLE SURGERY PACK FOR RADIAL ANGIOGRAPHY	86817441ST30100001422AD	SP-05004-68	T0202
DISPOSABLE ENT DRAPE 102X122 CM	86817441ST301000010209M	SD-04401-20	T0201
DISPOSABLE ENT PACK	86817441ST30100001767BJ	SP-04001-28	T0202
DISPOSABLE ENT SURGERY PACK	86817441ST30100002981BV	SP-04001-29	T0202
DISPOSABLE HIP SURGERY PACK	86817441ST30100001190AF	SP-07004-20	T0202
DISPOSABLE INSTRUMENT TABLE COVER 80X70 CM	86817441ST30100001999C9	SD-00200-13	T0201
DISPOSABLE LAPAROSCOPY PACK	86817441ST30100004140AM	SP-02005-45	T0202
DISPOSABLE LARGE SURGERY PACK	86817441ST30100002947BV	SP-02003-89	T0202
DISPOSABLE MINOR SURGERY PACK	86817441ST30100001776BK	SP-02003-90	T0202
DISPOSABLE PERSONAL PACK	86817441ST30100002689BW	SP-02003-91	T0202
DISPOSABLE PLAIN DRAPE 50X40 CM	86817441ST30100002251AH	SD-14209-46	T0201
DISPOSABLE REINFORCED SURGICAL GOWN - S	86817441ST30100002597BQ	SG-02222-01	T020402
DISPOSABLE REINFORCED SURGICAL GOWN - M	86817441ST30100003653BG	SG-02222-02	T020402
DISPOSABLE REINFORCED SURGICAL GOWN - L	86817441ST30100001593B9	SG-02222-03	T020402



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DISPOSABLE REINFORCED SURGICAL GOWN - XL	86817441ST30100004029AU	SG-02222-04	T020402
DISPOSABLE REINFORCED SURGICAL GOWN – XXL	86817441ST30100001595BD	SG-02222-05	T020402
DISPOSABLE REINFORCED SURGICAL GOWN - S	86817441ST30100004132AN	SG-02202-01	T020402
DISPOSABLE REINFORCED SURGICAL GOWN - M	86817441ST30100004133AQ	SG-02202-02	T020402
DISPOSABLE REINFORCED SURGICAL GOWN - L	86817441ST30100004134AS	SG-02202-03	T020402
DISPOSABLE REINFORCED SURGICAL GOWN - XL	86817441ST30100004135AU	SG-02202-04	T020402
DISPOSABLE REINFORCED SURGICAL GOWN – XXL	86817441ST30100004136AW	SG-02202-05	T020402
DISPOSABLE SPINAL PACK	86817441ST30100002682BG	SP-05010-24	T0202
DISPOSABLE STANDARD SURGICAL GOWN- S	86817441ST30100002167AT	SG-01201-01	T020401
DISPOSABLE STANDARD SURGICAL GOWN- M	86817441ST30100002168AV	SG-01201-02	T020401
DISPOSABLE STANDARD SURGICAL GOWN- L	86817441ST30100002705B3	SG-01201-03	T020401
DISPOSABLE STANDARD SURGICAL GOWN- XL	86817441ST30100004171AY	SG-01201-04	T020401
DISPOSABLE STANDARD SURGICAL GOWN- S	86817441ST30100001288AZ	SG-02201-01	T020401
DISPOSABLE STANDARD SURGICAL GOWN- M	86817441ST30100002393B6	SG-02201-02	T020401
DISPOSABLE STANDARD SURGICAL GOWN- L	86817441ST30100001921B4	SG-02201-03	T020401
DISPOSABLE STANDARD SURGICAL GOWN- XL	86817441ST30100001313A7	SG-02201-04	T020401
DISPOSABLE STANDARD SURGICAL GOWN- XXL	86817441ST30100004157B6	SG-02201-05	T020401
DISPOSABLE STANDARD SURGICAL GOWN- XXXL	86817441ST30100003986CE	SG-02201-06	T020401
DISPOSABLE STANDARD SURGICAL PACK	86817441ST30100002717BA	SP-02003-92	T0202
DISPOSABLE SUBCLAVIAN PACK	86817441ST30100002833BD	SP-02003-93	T0202
DISPOSABLE TUR PACK	86817441ST30100002007A4	SP-08003-91	T0202



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The products listed in the list above and their contents are classified Class 1 Sterile products. These products, their content, and their accessories do not take part in any other class. We herewith declare that the above mentioned products conforms general requirements of the Council Directive MDR 2017/745 ECC for all versions of Medical Device Directive .

Applied Directives

Medical Device Directive MDR 2017/745 ECC ANNEX XI A ALL VERSIONS.

DATE OF ISSUE : 25.08.2024

REV. NO. : 1

Name and Surname : Ieva Berke
Position : Sales Chief
Date of signature : 03.01.2024
Place of Signature : Kilis - Türkiye

